REMARKS

This Amendment is responsive to the Final Office Action, issued July 26, 2004, and the comments by the Examiner in the Advisory Action mailed December 3, 2004.

After entry of this Amendment, claims 1, 3, 8-28, and 123-125 will be pending. Claims 124 and 125 are newly added and are supported by disclosure throughout the specification, but in particular, by Examples 10 and 12. Applicants submit that neither the newly added claims nor any of the claim amendments add any new matter to the application.

Rejections under 35 U.S.C. §103(a)

In the final Office Action, claims 1, 3, 12-15, 20, and 23-28 were rejected under 35 U.S.C. §103(a) as unpatentable over WO 93/04692 (the "'692 publication") in view of the U.S. Patent No. 6,096,706 ("Toback"). Applicants amended independent claims 1 and 3 to more distinctly describe their claimed invention, and submit that the amended claims overcome this rejection for the following reasons.

The Examiner asserts that the '692 publication discloses regeneration of damaged tissue and that it provides examples for such regeneration after the onset of injury, and that it provides an example of creating a local defect site. Applicants respectfully submit that the '692 publication in view of Toback does not teach or suggest the claimed invention. The '692 publication does not disclose measuring the extent of tissue regeneration, but rather uses markers and changes in pathological conditions to gauge the effect of morphogen administration to induce tissue formation. The '692 publication also does not disclose administering a morphogen at least 6 hours after creating a local defect site. While the '692 publication describes administering a morphogen some time after renal injury, the publication does not specify at which time point such administration should occur. The timing of administration is important because, as described in the specification at page 5, lines 18 to 25, tissue repair is affected by the accessibility of progenitor cells to the defect site. Toback describes administering a therapeutic agent Wound Growth Factor, which is not a morphogen, one or two hours after subjecting rats to a toxin, and does not teach or suggest administering a single dose of a morphogen at least six hours after injury.

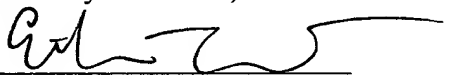
Therefore, Applicants submit that neither the '692 publication alone or in combination with Toback does not disclose all the limitations of the claims of the present application.

Claims 3, 6, and 8-28 were also rejected under 35 U.S.C. §103(a) as unpatentable over WO 93/04692 in view of Toback and Benet et al. Benet describes dosage optimization, but does not provide any information regarding timing or frequency of administration of a morphogen. Therefore, even if one skilled in the art was motivated to combine Benet with WO 93/04692 and Toback, Benet does not supplement the two other references with what is lacking from them, which is the timing and frequency of administration of a candidate morphogen.

In view of the above comments, Applicants believe that pending application is in condition for allowance, and respectfully request that the Examiner withdraw the rejections.

Dated: May 16, 2005

Respectfully submitted,

By 

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